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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Don	Alden	Sunnyvale, California

☐ Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR CARTRIDGE INDEXING

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS (check all that apply)

☑ Specification Number of Pages 7
☑ Drawing(s) Number of Sheets 11
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Application cover sheet; return postcard.

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____ Date 06/13/2003

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TELEPHONE (650) 324-7000 Docket Number: 38187-2685

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60478692.061303

Attorney Docket No.: 38187-2685

PROVISIONAL PATENT APPLICATION
METHOD AND APPARATUS FOR CARTRIDGE INDEXING

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PATENT

Attorney Docket No.: 38187-2685

METHOD AND APPARATUS FOR CARTRIDGE INDEXING

BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Another impediment to patient compliance is the lack of spontaneous blood flow generated by known lancing technology. In addition to the pain as discussed above, a patient may need more than one lancing event to obtain a blood sample since spontaneous blood generation is unreliable using known lancing technology. Thus the pain is multiplied by the number of attempts required by a patient to successfully generate spontaneous blood flow. Different skin thickness may yield different results in terms of pain perception, blood yield and success rate of obtaining blood between different users of the lancing device. Known devices poorly account for these skin thickness variations.

A still further impediment to improved compliance with glucose monitoring are the many steps and inconvenience associated with each lancing event. Many diabetic patients that are insulin dependent may need to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing, ranging from lancing, to milking of blood, applying blood to a test strip, and

getting the measurements from the test strip, discourages many diabetic patients from testing their blood glucose levels as often as recommended. Older patients and those with deteriorating motor skills encounter difficulty loading lancets into launcher devices, transferring blood onto a test strip, or inserting thin test strips into slots on glucose measurement meters. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved body fluid sampling device. An improved device for opening a sterile cavity on the cartridge and advancing the newly opening cavity into position with a penetrating member gripper. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue; a penetrating member coupler attached to said driver; and a cutting device that simultaneously cuts a sterility barrier on said cartridge while moving along a path that rotates the cartridge about its center to align the newly opened cavity in the cartridge with the penetrating member coupler.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. Some embodiments of the present invention provide an improved body fluid sampling device. For some embodiments of these penetrating member drivers, the invention relates to a new contact point algorithm that is run immediately before the actual lance event. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

Referring now to Figure 1, a top down view of one embodiment of a cartridge indexing device 10. The indexing device 10 include a cam groove 12. It moves a cutting element (see Figure 6) that opens a sterility barrier covering the cartridge 20. As seen in Figure 1, the path of pusher 22 is at a diagonal as indicated by arrow 24. Thus, as the pusher 22 is advanced outward, it both cuts the sterility barrier and it rotates the cartridge 20 since the pusher 22 is moving at a diagonal. A slider 30 may be use by the user to advance and move the pusher 22. A penetrating member driver 40 may be coupled drive the penetrating member gripper 50.

Figure 2 shows the penetrating member gripper 50 more clearly. This is the start and end position. As seen, the gripper 50 is in the cavity 52. The gripper 50 may be advanced outward as indicated by arrow 54 to direct the penetrating member into tissue. The punch 56, used to break the barrier covering the penetrating member exit, is in an up position to allow the penetrating member to exit. As seen in Figure 2, a second cam 60 is shown. The follower 62 is coupled to the sterility barrier cutter that cuts the barrier from the top and also rotates the cartridge 20. This cam 60 lowers the cutter on the forward stroke (to cut barrier and rotate cartridge) and raises it on the return stroke (so it does not rotate the cartridge back).

Figures 3 and 4 show the pusher 22 being advanced as indicated by arrow 70. Figure 4 shows the pusher 22 fully advanced. As seen, the punch 56 has dropped to open the front sterility barrier. The cutter 80 has moved from a rear of the cavity (Figure 3) to a front of the cavity (Figure 4).

Figure 5 shows a side view of the same position of the pusher 22 as that in Figure 4. As seen, the punch 56 has dropped, the cutter 80 has finished its stroke. The follower 62 is in the top groove of the cam 60. When the follower 62 drops to the bottom groove, the cutter 80 will be raised. As seen, the gripper 50 is in a raised position and allows the cartridge 20 to rotate.

Figure 6 is a close-up view of the second cam 60. It has a top groove 61 and bottom groove 63. The follower 62 travels through the grooves and flips the cutter 80 between up and down positions. In one embodiment, the follower 62 is in the top groove 61 in the forward stroke and in the bottom groove 63 in the backward stroke.

Referring now to the embodiment of Figure 7, the follower 62 has now moved to the bottom groove 63 and the cutter 80 is moved to an up position. The penetrating member coupler 50 is still in the up position.

Figure 8 shows the cutter 80 withdrawn, the punch 56 raised and the follower 62 in the bottom groove. In this embodiments, these motions are guided by cam surfaces. The coupler 50 is still raised.

Referring now to Figure 9, the follower 62 reaches the end of the bottom groove 63. The follower 90 (on pusher 22) pushes down on a cam surface (not shown) that lowers the gripper 50. In this position, the gripper 50 engages a penetrating member in the cavity and can actuate the member outward as indicated by arrow 100.

Figures 10 and 11 show still further views and embodiments of elements according to the present invention. This embodiment provides a simplified device the both indexes and cuts open the sterility barrier in a single motion. It should be understood that other element besides cams may be used to position the various elements. Rollers, gears, pulleys, electronic, or pneumatic actuators may be used.

Some embodiments may use a pneumatic actuator to advance the penetrating member. The same or a separate pneumatic actuator may be used withdraw the penetrating member. Any other actuator may be used in combination with the pneumatic or other actuator to effect a fast in slow out profile. The devices may be used in place of device 40.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. _____ Attorney Docket No. 38187-2551US and 38187-2606.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a penetrating member coupler attached to said driver;

a cutting device that simultaneously cuts a sterility barrier on said cartridge while moving along a path that rotates the cartridge about its center to align the newly opened cavity in the cartridge with the penetrating member coupler.

2. The device of claim 1 wherein the penetrating member driver is coupled to a position sensor, said sensor used to detect a position of the active one of said penetrating member.

3. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a penetrating member coupler attached to said driver;

a cutting device that simultaneously cuts a sterility barrier on said cartridge while moving along a path that rotates the cartridge about its center to align the newly opened cavity in the cartridge with the penetrating member coupler;

a display coupled to the driver for showing the number of lancets remaining.

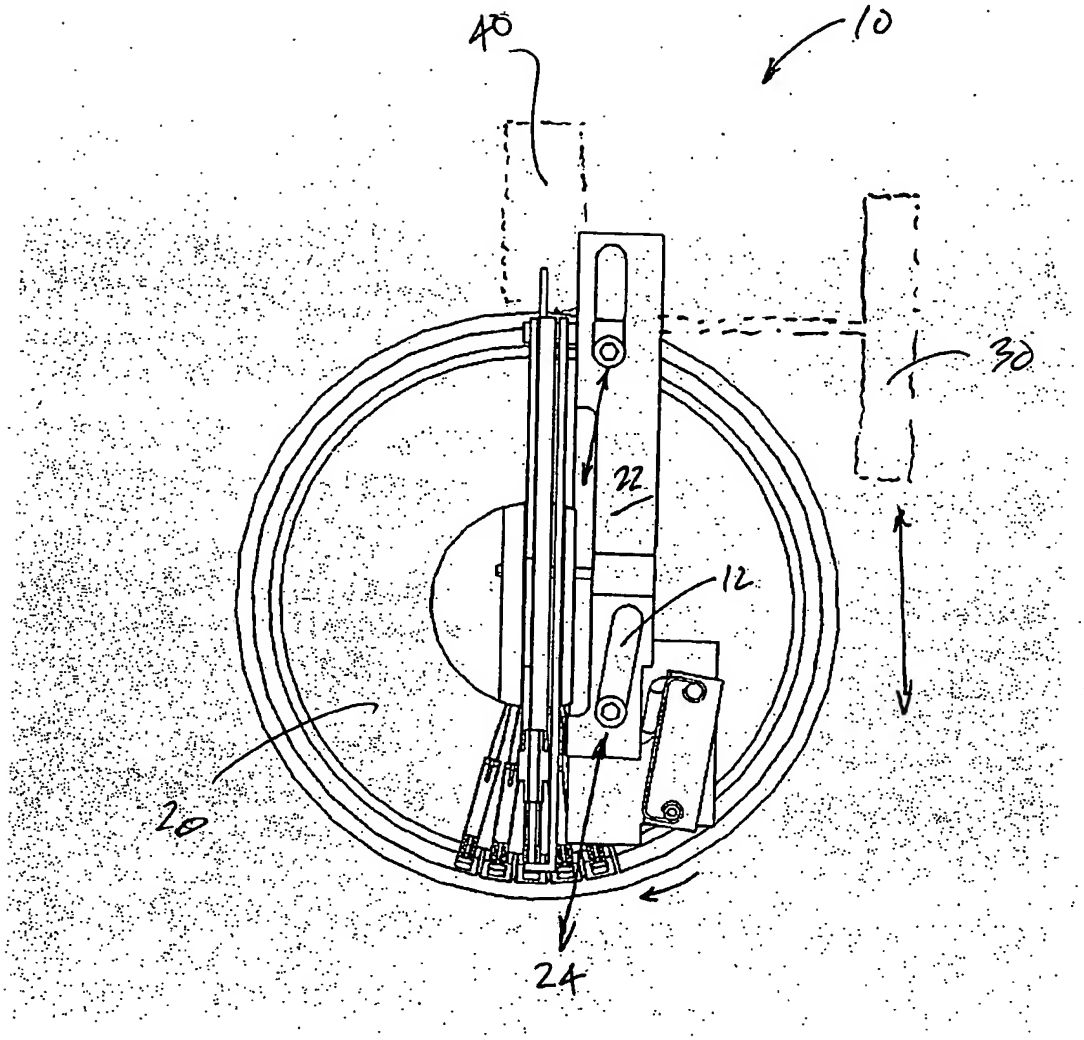

Figure 1

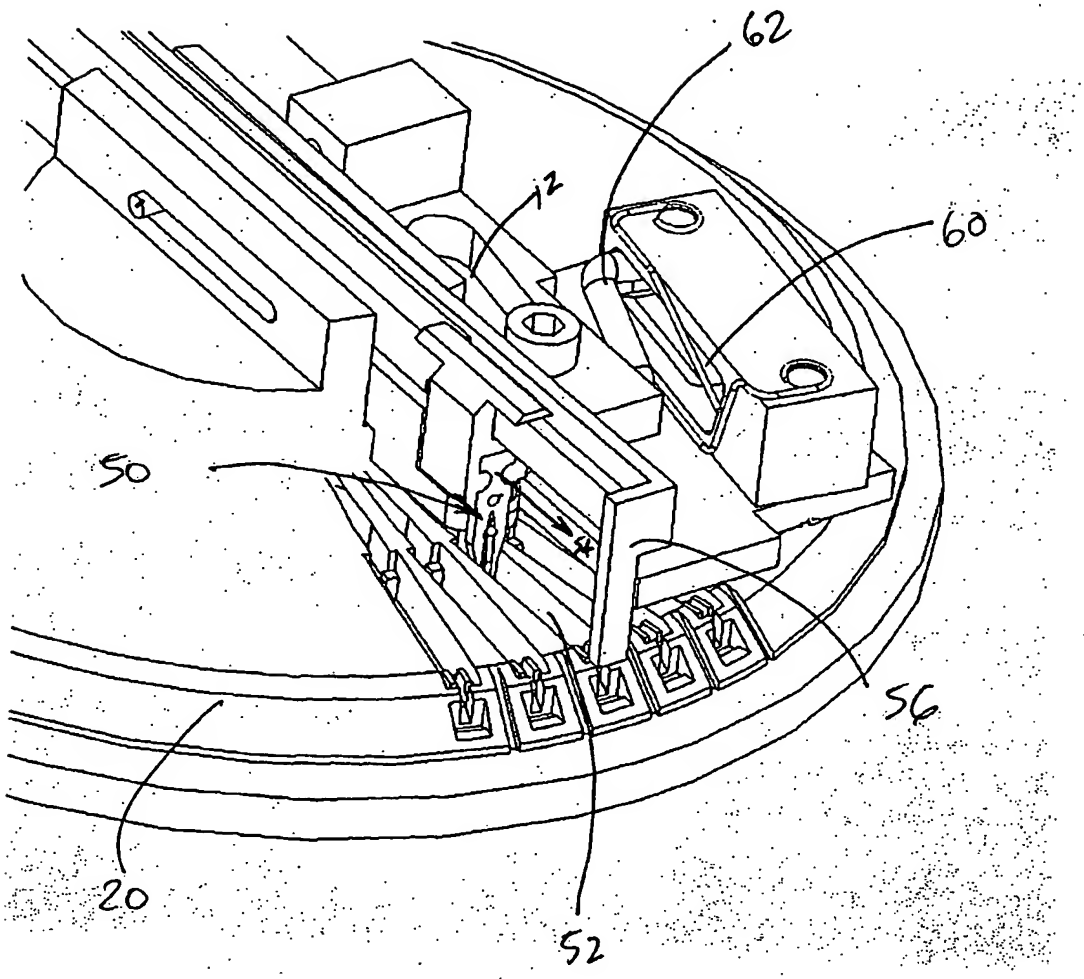

Figure 2

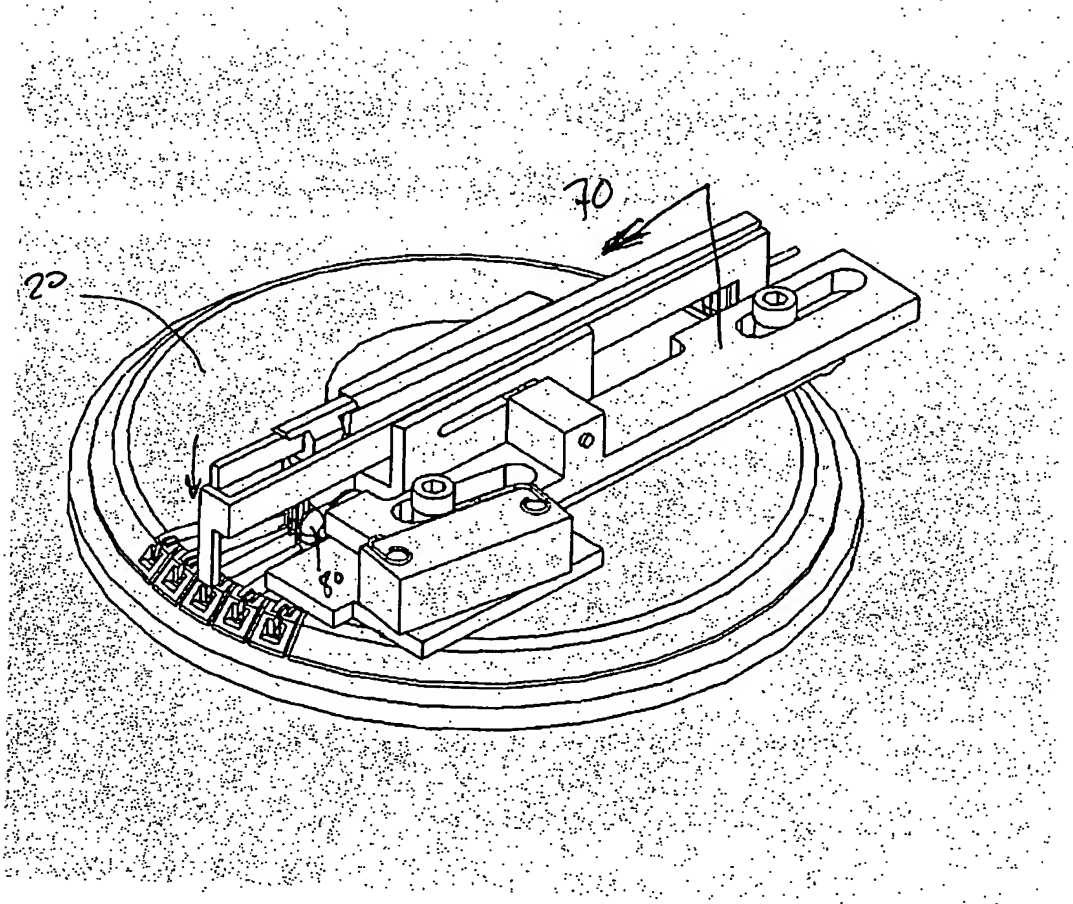

Figure 3

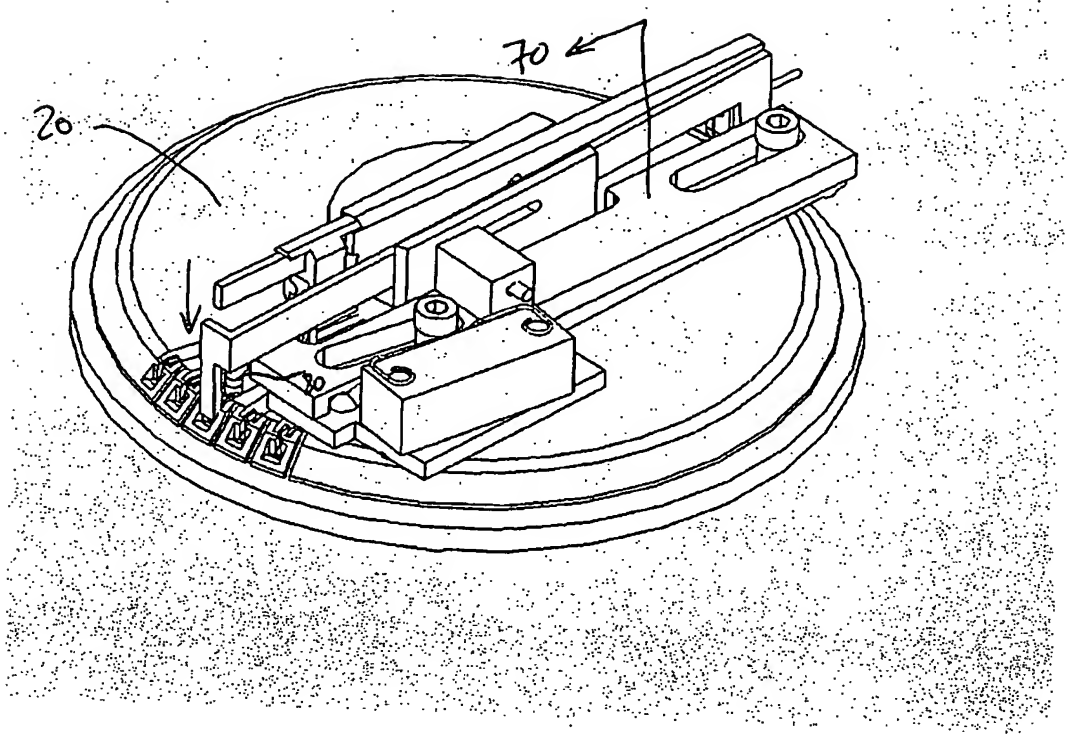

Figure 4

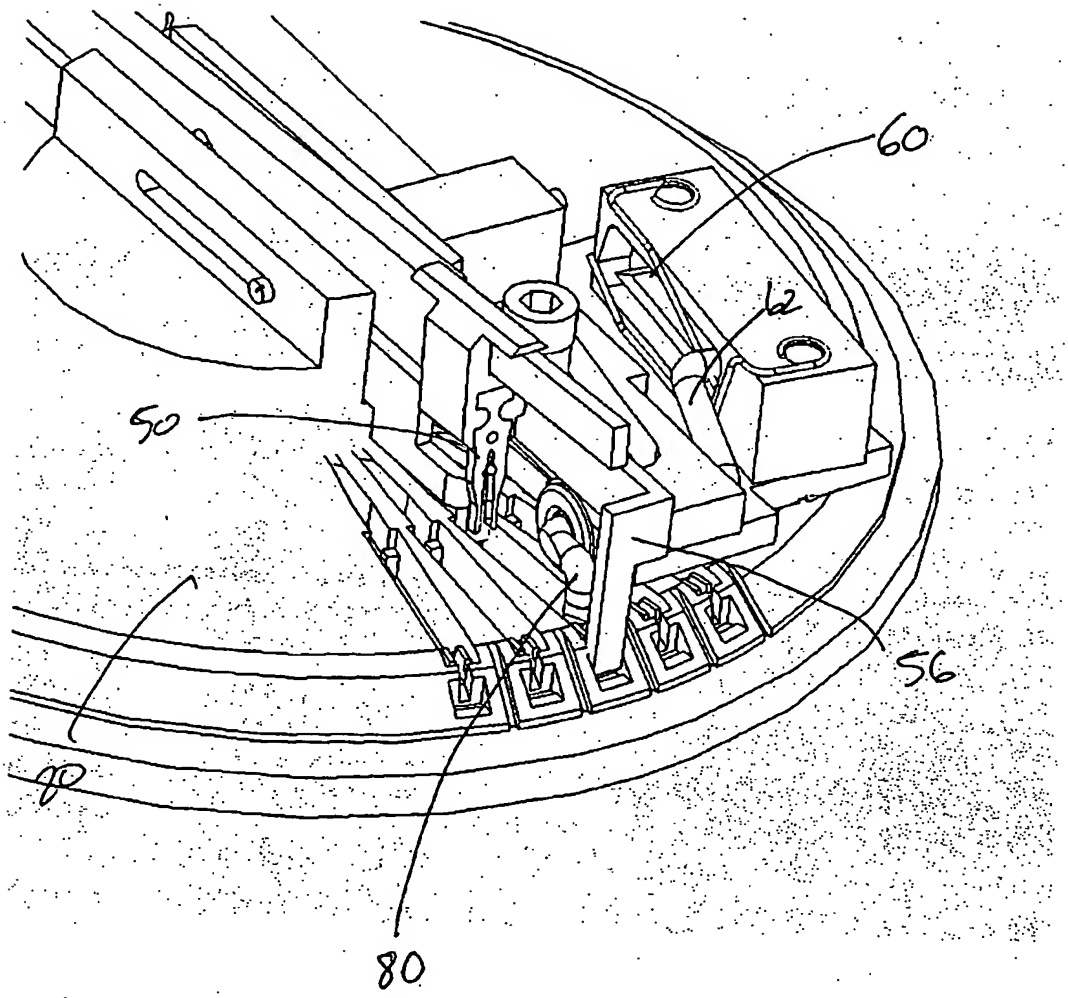

Figure 5

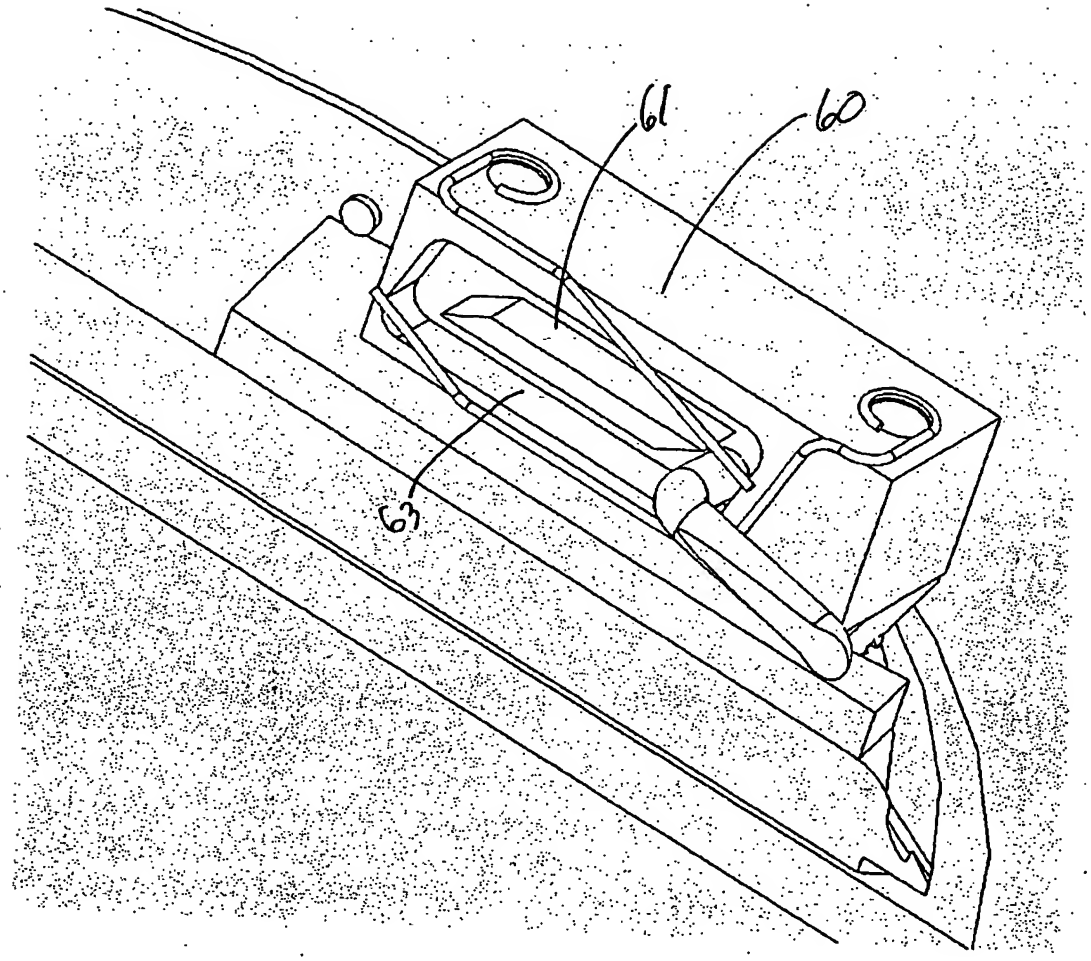

Figure 6

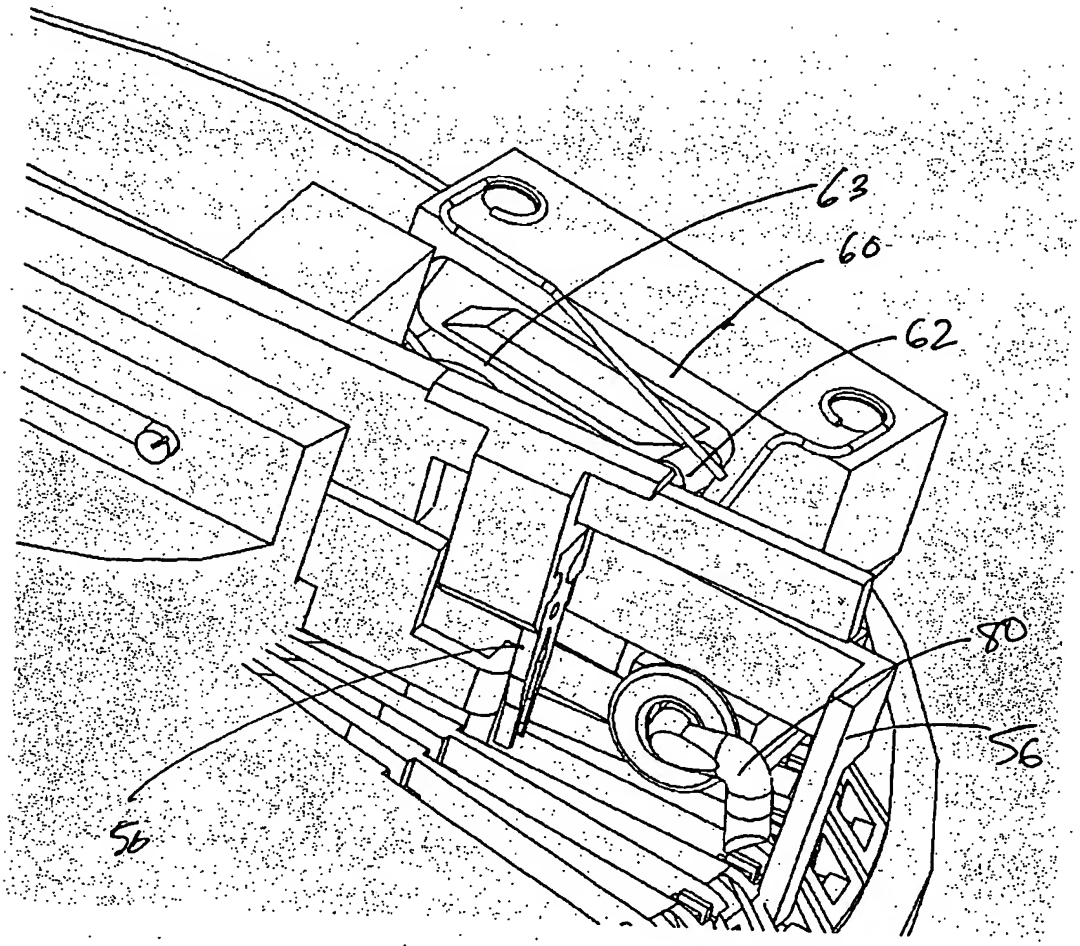

Figure 7

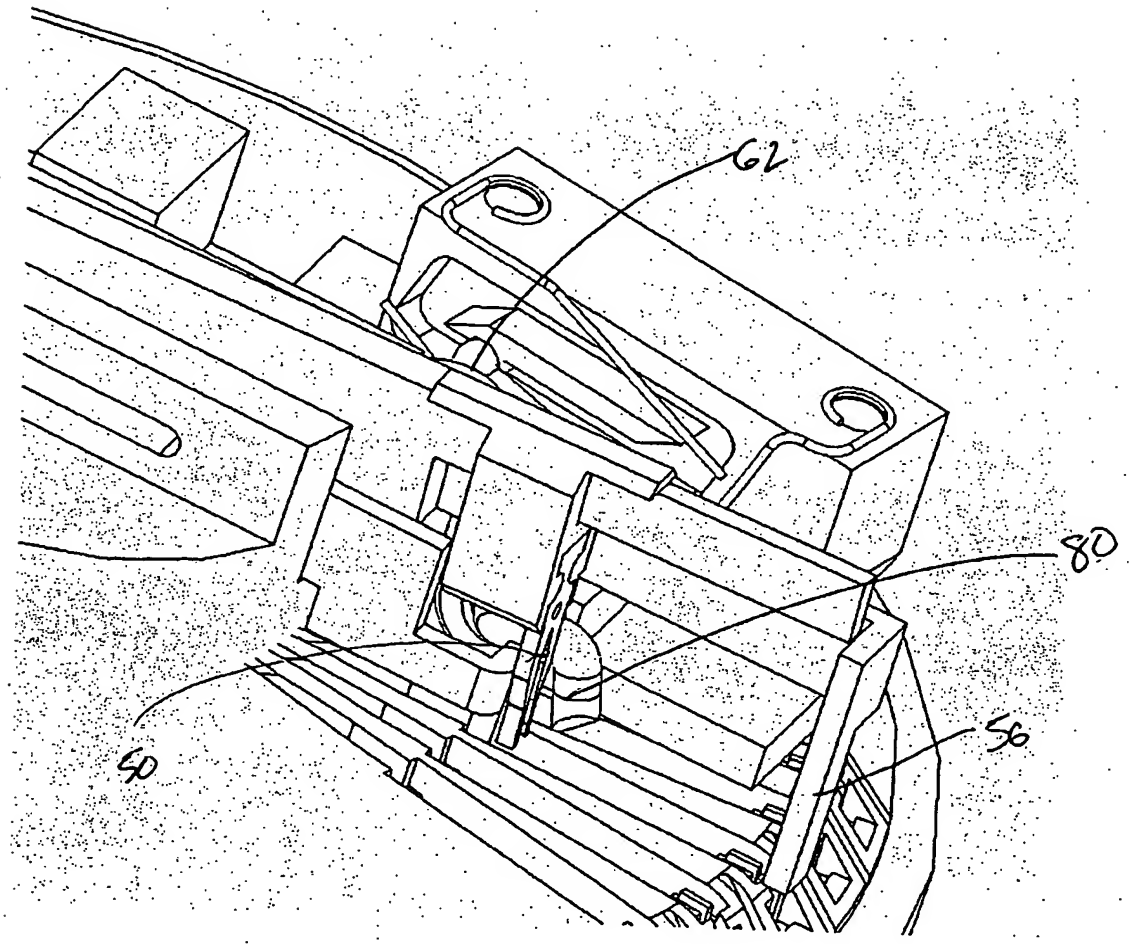

Figure 8

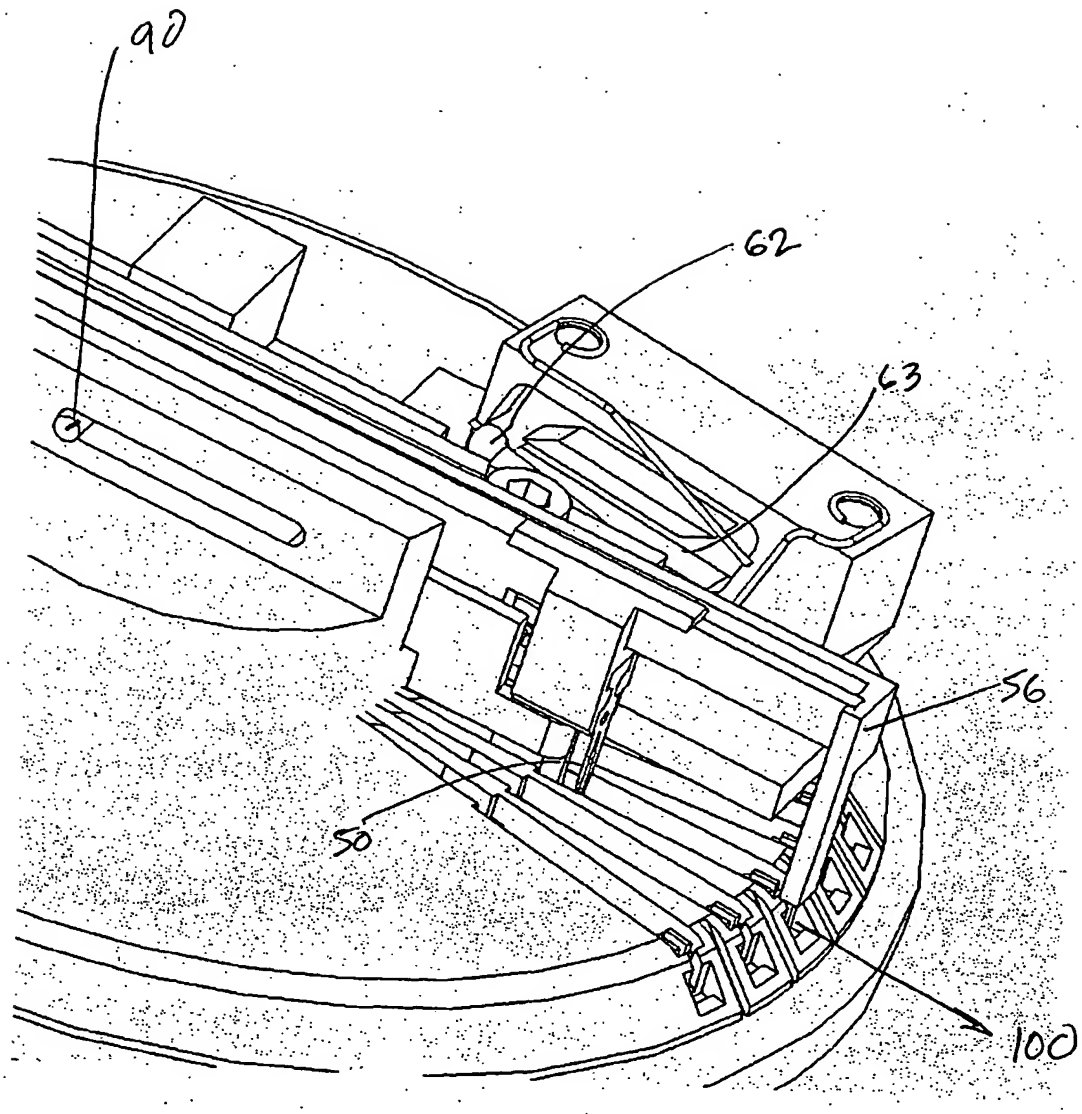

Figure 9

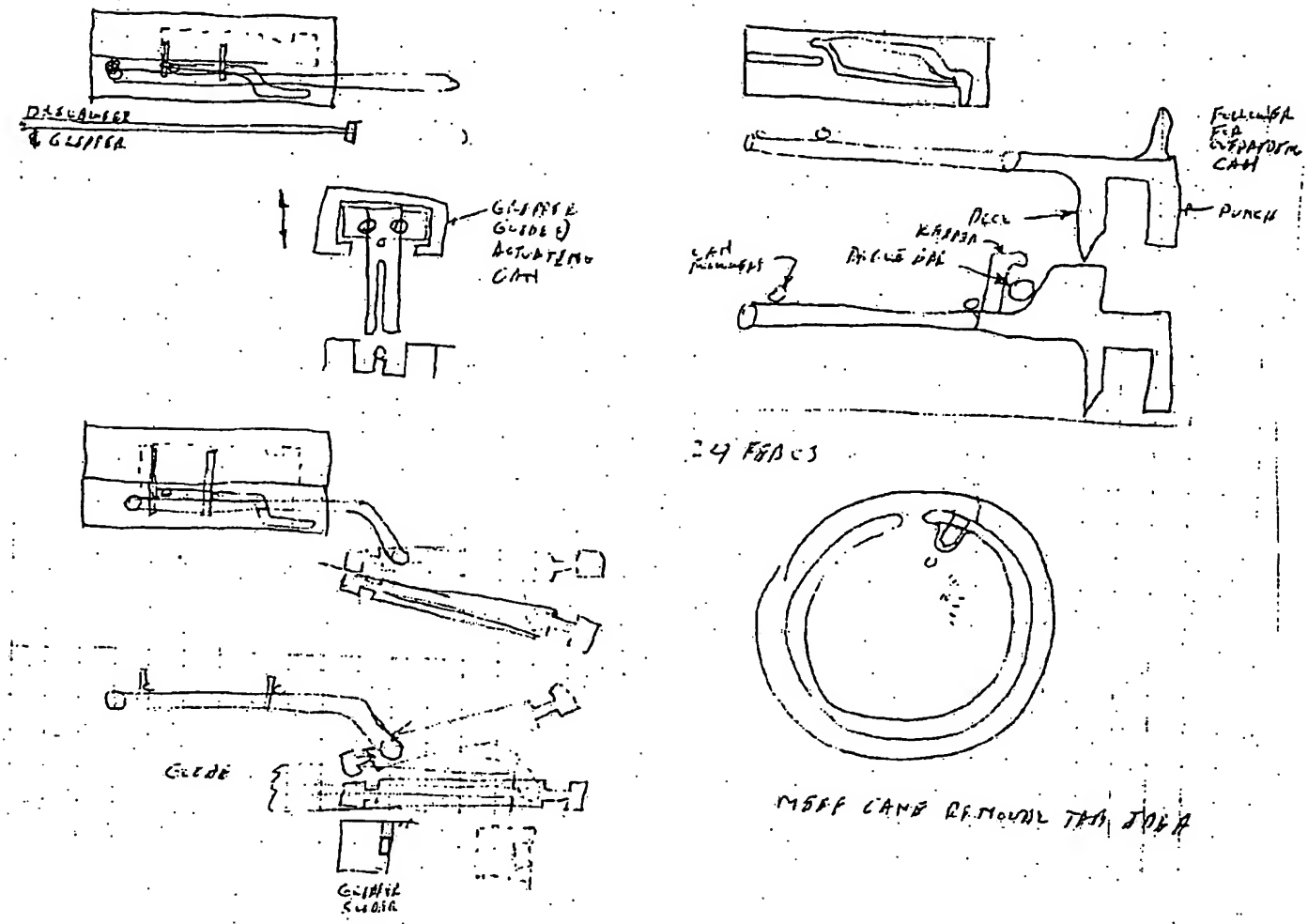
DISCHARGER
& GRIPPER
GRIPPER GUIDE & ACTUATING CAM
GUIDE
GRIPPER SLIDER
FOLLOWER FOR EXPANSION CAM
PUNCH
CAM FOLLOWER
24 FIBRES
MOVE CAM REMOVAL TAB DOWN

FIG_10

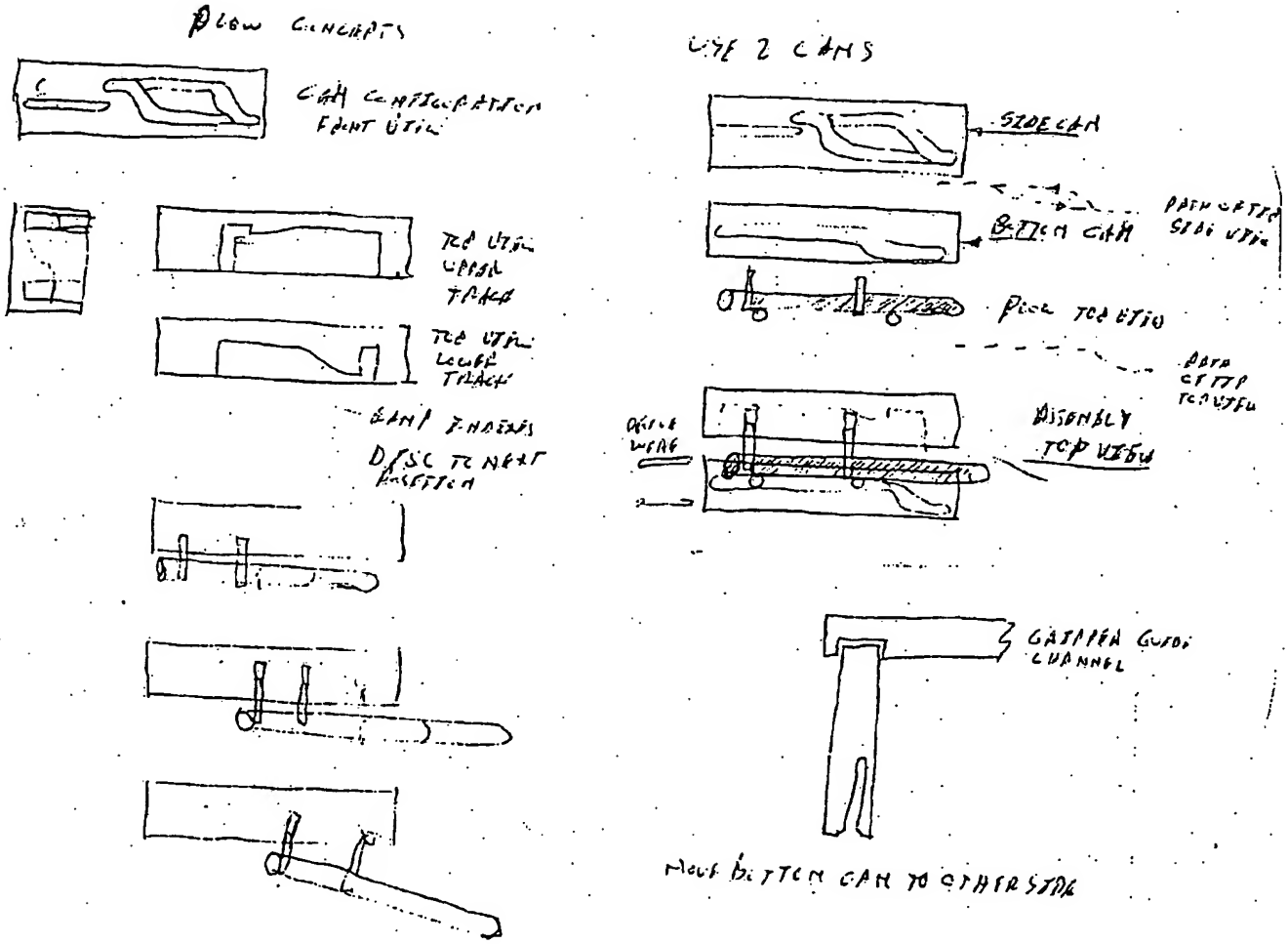
BLOW CONCEPTS
CAM CONFIGURATION FRONT VIEW
TOP VIEW UPPER TRACK
TOP VIEW LOWER TRACK
CAM FINGERS
DISC TO NEXT POSITION
USE 2 CAMS
SIDE CAM
PATH OF TIP SIDE VIEW
BOTTOM CAM
PICK TOP VIEW
PATH OF TIP TOP VIEW
DISENGAGE WEAK
DISENGAGE TOP VIEW
GRIPPER GUIDE CHANNEL
MOVE BOTTOM CAM TO OTHER SIDE

FIG_11